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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
BERMAN, A	
ART UNIT	**PAPER NUMBER**
1619	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/738,212	Applicant(s) NEUER ET AL.	
	Examiner Alysia Berman	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3,4,6 and 12-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7-11 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Receipt is acknowledged of the supplemental information disclosure statements filed April 13, 2001 and May 7, 2001 and the response filed June 6, 2001. Claims 1-19 are pending.

Election/Restrictions

2. Applicant's election of cyclosporin, the composition of claim 2 and gelatin capsules in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 3, 4, 6 and 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species of invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 10 recites FK 506, which is a tradename, and refers to European patents for active ingredients. It is improper to recite tradenames in claims and to refer to any examples in any specifications in the claims, especially foreign documents. Correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 5, 9, 10 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,047,396 (396).

US '396 discloses a pharmaceutical composition comprising 1 part cyclosporin, 8 to 13 parts of a polyethylene glycol saturated hydroxy fatty acid, and 4 to 10 parts of a mono- or polyvalent alcohol (abstract). Cyclosporin A, G, and C are suitable medicaments for the composition (col. 2, lines 44-47). Alcohols that may be present as co-solvents in the composition are ethanol and propylene glycol (col. 3, lines 1-5). Various excipients can be used in the formulation (col. 3, lines 15-16). Example 1 teaches 65 g of Solutol® HS 15 (polyethylene glycol-660-12-hydroxystearate), 30 ml of ethanol and 5 g of cyclosporin A. Ethanol is added to 100 ml. The composition of example 1 comprises 65% polyethylene glycol-660-12-hydroxystearate, 5% cyclosporin A and 30% ethanol. See also claim 6 for polyethylene glycol-660-12-hydroxy stearate

and claim 7 for ethanol and propylene glycol. No patentable weight is given to the preamble "for peroral administration" since this is an intended use.

9. Claims 1, 2, 5, 7-9 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,342,625 (625).

US '625 is directed to pharmaceutical compositions comprising cyclosporins (title). For Cyclosporin A and additional cyclosporins, see column 2, line 61 to column 3, line15. The composition comprises a hydrophilic phase, a lipophilic phase and a surfactant (col. 6, lines 45-50). For propylene glycol as the hydrophilic phase, see column 7, lines 21-25. For additional alcohols in the hydrophilic phase such as ethanol, see column 8, lines 25-35. For polyoxyethylene stearic acid esters as surfactants, see column 9, lines 40-44 and column 10, lines 31-32. US '625 teaches at column 12, lines 16-17 that the composition may contain a single surfactant, i.e. a polyoxyethylene stearic acid ester. For hard and soft gelatin capsules, see column 16, lines 25-28. For ratios of components, see column 17, line 50 to column 18, line 20. The ratio of cyclosporin (a) to hydrophilic phase (c) is 1:0.2-10 p.p.w. (col. 17, lines 50-54). The ratio of cyclosporin to surfactant (b) is 1:0.5-20 (col. 18, lines 13-20). Therefore, the ratio of (a):(b):(c) is 1: 0.5-20: 0.2-10, which overlaps the instantly claimed ratios. US '625 teaches fatty acid triglycerides (triesters of fatty acids) as the lipophilic phase at column 8, lines 56-65 and mono-, di- and mono/diglycerides as surfactants at column 11, lines 36-52.

10. The limitations of claims 17 and 18 pertaining to how the polyethoxylated saturated hydroxy fatty acid is obtainable are not given patentable weight. The claims

are product-by-process claims that are directed to a composition. How the composition or components in the composition can be obtained does not render the composition patentable over the prior art.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 2, 5, 7-11 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,047,396 (396) in combination with US 5,342,625 (625).

US '396 and US '625 teach all the limitations of the claims as stated above. US '396 does not teach the composition in a capsule. US '625 does not teach polyethylene glycol-660-12-hydroxy-stearate. Each reference makes up the deficiencies of the other.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '396 in a capsule as taught by US '625 with the reasonable expectation of obtaining a cyclosporin composition that provides convenient oral administration and improved bioavailability.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 2, 5, 7-11 and 17-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/690400. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to compositions comprising cyclosporin, a C_2-C_3 alcohol and a surfactant. The applications differ in that 09/690400 is claiming also a mixed mono-, di-, triglyceride. The instant application discloses mono-, di-, and triesters of fatty acids for use in the compositions. See claim 3. Glycerides are esters. It would have been obvious

to one of ordinary skill in the art at the time of the invention to make the composition of the instant application and add mixed mono-, di-, triglyceride as disclosed in 09/690,400 expecting to obtain a oral dosage form containing cyclosporin .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1, 2, 5, 7-11 and 17-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 09/605512. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a composition comprising cyclosporin a polyethoxylated hydroxy fatty acid ester surfactant and an alcohol.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1, 2, 5, 7-11 and 17-19 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 15, 17, 19, 24, 26 and 28 of copending Application No. 09/547802. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a composition comprising cyclosporin, an alcohol and a surfactant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

Alysia Berman
Patent Examiner
July 11, 2001

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